

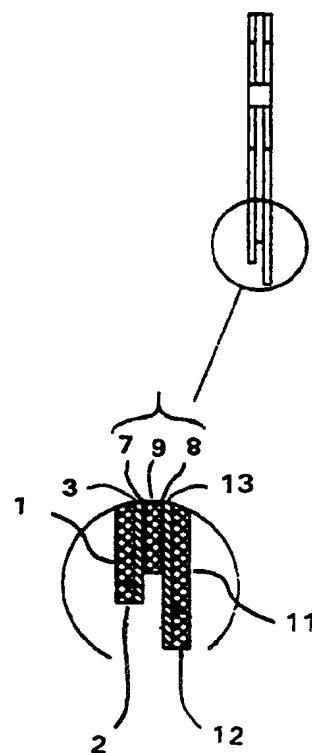


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/AU98/00200 (22) International Filing Date: 25 March 1998 (25.03.98) (30) Priority Data: PO 5857 25 March 1997 (25.03.97) AU (71) Applicant (for all designated States except US): MEMTEC AMERICA CORPORATION [US/US]; Suite 700, 9690 Deereco Road, Timonium, MD 21093 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): HODGES, Alastair, McIndoe [AU/AU]; 15 Jasmine Court, Blackburn South, VIC 3130 (AU). BECK, Thomas, William [AU/AU]; 31 Drummond Street, South Windsor, NSW 2756 (AU). MAXWELL, Ian, Andrew [AU/AU]; 3 Whiting Street, Leichhardt, NSW 2040 (AU). (74) Agent: SHELSTON WATERS; 60 Margaret Street, Sydney, NSW 2000 (AU).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: IMPROVED ELECTROCHEMICAL CELL**(57) Abstract**

The invention relates to an amperometric electrochemical cell having a first insulating substrate (1) carrying a first electrode (2), a second insulating substrate (11) carrying a second electrode (10), said electrodes being disposed to face each other and spaced apart by less than 500 μm , and defining a sample reservoir (4) therebetween, and wherein at least one, and preferably both, insulating substrates and the electrode carried thereon include an electromagnetic radiation transmissive portion in registration with said reservoir. The walls of the electrochemical cell (2, 12) may be formed from a thin metallic portion (3) on a transparent substrate (1). Such cells are useful in providing visual confirmation of the validity of the electrochemical measurement.



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"IMPROVED ELECTROCHEMICAL CELL"

Technical Field

This invention relates to disposable electrochemical sensors of the type used for
5 quantitative analysis, for example, of glucose levels in blood, or the like.

Background Art

Light transmissive electrodes are known in the prior art, however they have not
previously been applied to amperometric cells. For example, GB 2 194 112 discloses the
use of optically transparent electrodes used to drive a microelectrophoresis cell while laser
10 doppler velocimetry is used to determine the velocity and micro current motion of charged
particles within the sample.

JP, A 05080018 discloses another approach to making transparent electrodes by the
use of conductive glass for electrochromic and field emission devices.

JP, A 06310746 also teaches the use and formation of yet another type of
15 conducting transparent electrode formed from the deposition of organic conducting
polymers onto a glass slide. This type of electrode is useful in solar energy collection cells.
Ullery, in US 4,254,546 also discloses a photovoltaic cell in which the top layer is a light
collecting electrode.

US 4,782,265 discloses two spaced apart translucent electrodes useful in luminescent
20 cells. However, US 4,782,265 specifically teaches that gold, silver, aluminium, platinum
and the like are only suitable for the production of non-transmissive electrodes.

In co-pending applications PCT/AU96/00207, PCT/AU96/00365, PCT/AU96/00723
and PCT/AU96/00724 (the contents of which are incorporated herein by reference) there
are described various very thin electrochemical sensors or cells. These cells are by a pair

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of oppositely facing spaced apart electrodes which are formed as thin metal coatings (for example sputter coatings) deposited on thin inert plastic film (for example 100 micron thick PET). The electrodes are separated one from the other by a spacer of thickness of for example 500 μm or less.

5 Such cells may be provided with one or more fluid passageways into and out of the sample reservoir whereby the cell may be filled with an analyte and air expelled during filling. In some embodiments the analyte is drawn into the cell by the energy liberated as a reagent contained therein dissolves.

10 The sensors are, as discussed above, very small and normally contain only small amounts of the liquid sample. Accurate measurement requires that the cell be filled with liquid. Even minute variations in the quantity of liquid in the cell can effect the sensing measurements. It can be difficult for a user to be sure that in use the cell has been uniformly filled with a sample to be analysed.

15 Further, sensors of the kind under discussion are usually intended to be discarded after use. If a user is distracted after use or prior to disposal it is not always easy for the user to know which sensors have been used and which have not.

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

Disclosure of the Invention

20 According to one aspect the present invention provides an amperometric electrochemical cell comprising a first insulating substrate carrying a first electrode, a second insulating substrate carrying a second electrode, said electrodes being disposed to face each other and spaced apart by less than 500 μm , and defining a sample reservoir therebetween, wherein at least one of said insulating substrates and the electrode carried

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thereon includes an electromagnetic radiation transmissive portion in registration with said reservoir.

Preferably, both said insulating substrates and the electrodes thereon include a transmissive portion. Most preferably, the transmissive portion is formed by a conductive
5 metallic coating on the substrate, which is of a thickness such that it is transparent or translucent. Suitable substances for the metallic coating include gold, indium oxide, tin oxide or mixtures thereof. A suitable substrate is PET.

According to a second aspect, the invention provides a method of filling an amperometric cell comprising the steps of:

- 10 a) drawing a liquid sample into said cell comprising a first insulating substrate carrying a first electrode, a second insulating substrate carrying a second electrode, said electrodes being disposed to face each other and spaced apart by less than 500 μm , and defining a sample reservoir therebetween, wherein at least one of said insulating substrates and the electrode carried thereon includes an electromagnetic radiation transmissive portion in
15 registration with said reservoir
- b) exposing the transmissive portion to electromagnetic radiation
- c) monitoring a property of the electromagnetic radiation passing and/or reflected through said transmissive portion
- d) comparing said monitored property with a predetermined value indicative of the cell
20 being filled, and
- e) continuing to draw the liquid sample into the cell until said monitored property reaches said predetermined value.

According to a third aspect, the invention provides a method of determining whether an amperometric cell is filled with a liquid sample, said cell comprising a first insulating

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- substrate carrying a first electrode, a second insulating substrate carrying a second electrode, said electrodes being disposed to face each other and spaced apart by less than 500 μm , and defining a sample reservoir therebetween, wherein at least one of said insulating substrates and the electrode carried thereon includes an electromagnetic radiation transmissive portion in registration with said reservoir, said method comprising the steps of:
- a) exposing said transmissive portion to electromagnetic radiation,
 - b) monitoring a property of the electromagnetic radiation passing and/or reflected through said transmissive portion, and
 - 10 c) comparing said monitored property with a predetermined value indicative of the cell being filled.

Suitable forms of electromagnetic radiation include visible, ultraviolet, infra-red and laser light. Daylight is especially preferred. The monitored property can include optical density, wavelength, refractive index and optical rotation.

- 15 In preferred embodiments, it is envisaged that the sample will be blood. The electromagnetic property may be monitored inside (for instance with a fibre optical device) or outside the cell, and the electromagnetic radiation may pass substantially directly through the cell or be internally reflected within the cell.

- According to a fourth aspect, the invention consist in a method for monitoring an
20 analyte in a liquid sample comprising the steps of :

- a) drawing the sample into an amperometric electrochemical cell comprising a first insulating substrate carrying a first electrode, a second insulating substrate carrying a second electrode, said electrodes being disposed to face each other and spaced apart by less than 500 μm , and defining a sample reservoir therebetween, wherein at least one of said

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insulating substrates and the electrode carried thereon includes an electromagnetic radiation transmissive portion in registration with said reservoir,

- b) exposing the transmissive portion to electromagnetic radiation
- c) monitoring a property of the electromagnetic radiation passing and/or reflected
5 through said transmissive portion
- d) comparing said monitored property with a predetermined value indicative of the cell being filled, and
- e) prior to, simultaneously with or after any one of steps b) to d) applying a potential across the electrochemical cell and measuring the resultant current to detect the
10 analyte.

The method of the above aspect may also further comprise the step of:

- f) repeating steps a) to e) until the monitored property reaches the predetermined value.

In one preferred embodiment, the method is repeated on different cells, with blood as
15 the sample and visible light the electromagnetic radiation, until a valid measurement is obtained for blood glucose.

In a fifth aspect, the invention provides an apparatus for determining whether an amperometric cell according to the first aspect is filled with a liquid sample, said apparatus comprising an electromagnetic radiation means adapted to expose said transmissive portion
20 of said cell to electromagnetic radiation,
a monitoring means adapted to monitor a property of the electromagnetic radiation passing and/or reflected through said transmissive portion, and
a means for determining whether said monitored property has reached a predetermined value indicative of the cell being filled.

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Preferably, said apparatus may also include means to apply potential across the amperometric cell and detect the resultant current. It may also include a validation means to confirm the cell is filled with a liquid sample.

“Comprising” as herein used is used in an inclusive sense, that is to say in the sense of “including” or “containing”. The term is not intended in an exclusive sense (“consisting” of or “composed of”).

Light-transmissive cells intended for spectrophotometric use are well known. However this has not previously been accomplished in a cell wherein the only surfaces suitable for a window are entirely covered by a metal electrode. One skilled in the art will appreciate that whilst the embodiments of the invention are described with respect to light transmissive conductive coatings, such coatings may be also be transparent to some other forms of electromagnetic radiation which are not visible to the human eye.

Best Mode for Carrying out the Invention

The invention will now be particularly described by way of example only reference to the accompanying schematic drawings wherein:

Figure 1 shows a cross section of a wall of a cell according to the present invention.

Figure 2 shows a cell according to one embodiment of the present invention.

Figure 3 shows a cross section of the cell in Figure 2.

An embodiment of the invention will now be described by way of example only.

Referring firstly to figure 1, each wall of the cell 2,12 comprises an insulating substrate 1,11 carrying an electrode 3,13 thereon.

The embodiment is generally in accordance with the apparatus described in our co-pending application PCT/AU96/00724 which is incorporated herein by reference. The apparatus hereof corresponds substantially to the apparatus described in that application

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with the difference that electrode layer 3,13 which in application PCT/AU96/00724 was sputter coated palladium having a thickness of 100-1000 Angstrom, is replaced according to the present invention, by a light-transmissive conductive metallic coating of a thickness such that it is transparent or translucent. Gold, indium oxide, tin oxide and mixtures of
5 indium and tin oxides or other suitable light-transmissive conductive metallic coating may be utilised. Those skilled in the art will appreciate that transparent inorganic and organic polymers or mixtures thereof could also be used. Substrate 1 is also light-transmissive.

In one embodiment, the cell takes the form as shown in Figures 2 or 3. The cell comprises a first insulating substrate 1 consisting of a Melinex[®] PET layer, a first electrode
10 3 consisting of a conductive metallic layer on substrate 1, an adhesive layer 7, a PET spacer 9, a second adhesive layer 8, a second electrode 13 formed as a metallic layer formed as a metallic coating on second insulating substrate 11. Spacer 9 defines a sample reservoir 4 having a thickness corresponding to the thickness of the spacer 9 together with the thickness of adhesive layers 7 and 8. Access to the sample reservoir 4 is provided at
15 the side edge of the cell by notches 6.

At least one of the said insulating substrates and the electrode carried thereon includes an electromagnetic radiation transmissive portion 20 in registration with the reservoir 4.

In preferred embodiments of the invention, a sample to be analysed is introduced
20 to the cell by capillary action. The sample is placed on contact with notch 6 and is spontaneously drawn by capillary action into the reservoir 4, displaced air from the reservoir 4 venting from the opposite notch 6. A surfactant may be included in the capillary space to assist in drawing in the sample.

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The cell is provided with connection means for example edge connectors whereby the cell may be placed into a measuring circuit. In a preferred embodiment this is achieved by making spacer 9 shorter than cell walls 2, 12 and by making one wall 2 of shorter length than the other 12. This forms a socket region having contact areas electrically connected
5 with the working and counter electrodes of a sensing apparatus. A simple tongue plug having corresponding engaging conduct surfaces can then be used for electrical connection. Connectors of other form may be devised.

Chemicals for use in the cell may be supported on the cell electrodes or walls, may be supported on an independent support contained within the cell or may be self-
10 supporting.

In use, when the cell is filled with the liquid sample, e.g. blood, a film of the sample covers the inside of the transmissive portion 20 formed by substrate 1,11 and metal electrode 3,13 over reservoir 4, thereby indicating to the user when the cell is adequately filled, and clearly differentiating a used sensor from an unused one.

15 Apart from simple visual inspection, a user can also monitor the filling of the cell by exposing the electromagnetic radiation transmissive portion 20 to electromagnetic radiation such as infra-red, ultraviolet light or laser light and monitoring a property of the electromagnetic radiation (for example, optical density, colour or optical rotation) as it exits the cell, either by another transmissive portion on the opposite side of the reservoir, or
20 as a result of internal reflection within the reservoir.

A particular embodiment of an apparatus suitable for carrying out the inventive method is hereby described. The apparatus has means for holding and orienting a cell according to the present invention and exposing the electromagnetic portion of the cell to allow an electromagnetic radiation source, e.g. a light beam, to enter the reservoir.

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Optionally, the apparatus may also be equipped with means for automatically placing the cells into the said holding means.

The path of the light beam is substantially linear, and it exits the cell either via another transparent portion of the cell, or is reflected back through the first mentioned transmissive portion. The electromagnetic radiation leaving the cell is monitored by an appropriate detector. This detector monitors a property of the electromagnetic radiation leaving the cell for comparison with a predetermined value which is indicative of the cell being filled, for example if the cell is filled with blood up to or above the transmissive portion, a reduction in optical density will be detected. If the cell is empty or only partially filled to this point, the optical density will remain high but will reduce as the reservoir is filled until it reaches the predetermined value indicating a full cell. It will be appreciated that the apparatus could be made to continue filling until the cell was satisfactorily filled, by means of a feedback system. The apparatus could also be adapted so that it performed the necessary electrochemical measurements on the cell, thus reducing the need for excessive sample movement.

The apparatus preferably also includes a validation means which is triggered when it is determined that the cell is full and the sensing measurement can be accepted as valid.

As will be apparent to those skilled in the art from the teaching hereof the invention may be embodied in other forms without departing herefrom.

CLAIMS

1. An amperometric electrochemical cell comprising a first insulating substrate carrying a first electrode, a second insulating substrate carrying a second electrode, said electrodes being disposed to face each other and spaced apart by less than 500 μm , and defining a sample reservoir therebetween, wherein at least one of said insulating substrates and the electrode carried thereon includes an electromagnetic radiation transmissive portion in registration with said reservoir.
2. An amperometric electrochemical cell according to claim 1 wherein both of said insulating substrates and the electrodes carried thereon include a transmissive portion.
3. An amperometric electrochemical cell according to claim 1 or claim 2 wherein the electromagnetic radiation transmissive portion of each electrode is formed by a conductive metallic coating on said substrate(s).
4. An amperometric electrochemical cell according to claim 3 wherein the conductive metallic coating is of a thickness such that it is transparent or translucent.
5. An amperometric electrochemical cell according to claims 3 or 4 wherein the metallic coating is selected from one or more members of the group consisting of: gold, indium oxide, tin oxide and mixtures thereof.
6. An amperometric electrochemical cell according to any one of the preceding claims wherein the insulating substrate(s) is/are PET.
7. A method of filling an amperometric cell comprising the steps of:
 - a) drawing a liquid sample into said cell comprising a first insulating substrate carrying a first electrode, a second insulating substrate carrying a second electrode, said electrodes being disposed to face each other and spaced apart by less than 500 μm , and defining a sample reservoir therebetween, wherein at least one of said insulating substrates and the

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electrode carried thereon includes an electromagnetic radiation transmissive portion in registration with said reservoir

b) exposing the transmissive portion to electromagnetic radiation

c) monitoring a property of the electromagnetic radiation passing and/or reflected through
5 said transmissive portion

d) comparing said monitored property with a predetermined value indicative of the cell being filled, and

e) continuing to draw the liquid sample into the cell until said monitored property reaches said predetermined value.

10 8. A method of determining whether an amperometric cell is filled with a liquid sample, said cell comprising a first insulating substrate carrying a first electrode, a second insulating substrate carrying a second electrode, said electrodes being disposed to face each other and spaced apart by less than 500 μm , and defining a sample reservoir therebetween, wherein at least one of said insulating substrates and the electrode carried thereon includes
15 an electromagnetic radiation transmissive portion in registration with said reservoir, said method comprising the steps of:

a) exposing said transmissive portion to electromagnetic radiation,

b) monitoring a property of the electromagnetic radiation passing and/or reflected through said transmissive portion, and

20 c) comparing said monitored property with a predetermined value indicative of the cell being filled.

9. A method according to claim 7 or 8 wherein the electromagnetic radiation is selected from the group consisting of visible light, ultraviolet, infra-red, laser

10. A method according to claim 9 wherein the visible light is daylight

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11. A method according to any one of claims 7 to 10 wherein said monitored property is selected from the group consisting of optical density, wavelength, refractive index and optical rotation.
12. A method according to any one of claims 7 to 11 wherein the liquid sample is
5 blood.
13. A method according to any one of claims 7 to 12 wherein the electromagnetic property is monitored outside the cell.
14. A method according to any one of claims 7 to 12 wherein the electromagnetic property is monitored inside the cell.
- 10 15. A method according to claim 13 wherein the electromagnetic radiation passing substantially directly through the sample is monitored.
16. A method according to claim 13 wherein the electromagnetic radiation reflected internally in the cell is monitored.
17. A method according to claim 14 wherein the electromagnetic property is observed
15 by a fibre optical device.
18. A method for monitoring an analyte in a liquid sample comprising the steps of :
- a) drawing the sample into an amperometric electrochemical cell comprising a first insulating substrate carrying a first electrode, a second insulating substrate carrying a second electrode, said electrodes being disposed to face each other and spaced apart by less
20 than 500 μm , and defining a sample reservoir therebetween, wherein at least one of said insulating substrates and the electrode carried thereon includes an electromagnetic radiation transmissive portion in registration with said reservoir,
- b) exposing the transmissive portion to electromagnetic radiation

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c) monitoring a property of the electromagnetic radiation passing and/or reflected through said transmissive portion

d) comparing said monitored property with a predetermined value indicative of the cell being filled, and

5 e) prior to, simultaneously with or after any one of steps b) to d) applying a potential across the electrochemical cell and measuring the resultant current to detect the analyte.

19. A method according to claim 18 further comprising the step of

f) repeating steps a) to e) until the monitored property reaches the predetermined
10 value.

20. A method according to claim 19 wherein steps a) to e) are repeated on the same cell.

21. A method according to claim 19 wherein steps a) to e) are repeated on a new cell.

22. A method according to claim 19 wherein the sample is blood.

15 23. A method according to claim any one of claims 18 to 22 wherein the electromagnetic radiation is visible light.

24. A method according to any one of claims 18 to 23 wherein the monitored property is selected from the group consisting of optical density, wavelength, refractive index and optical rotation.

20 25. A method according to any one of claims 18 to 24 wherein the analyte is glucose.

26. An apparatus for determining whether an amperometric cell according to any one of claims 1 to 6 is filled with a liquid sample, said apparatus comprising an electromagnetic radiation means adapted to expose said transmissive portion of said cell to electromagnetic radiation,

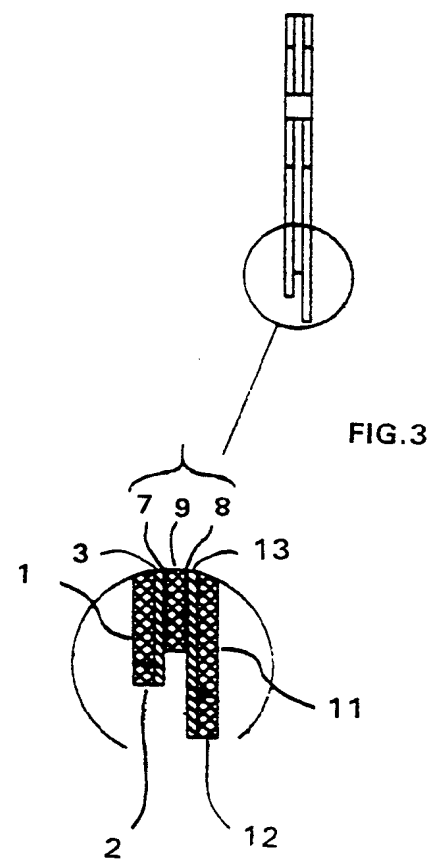
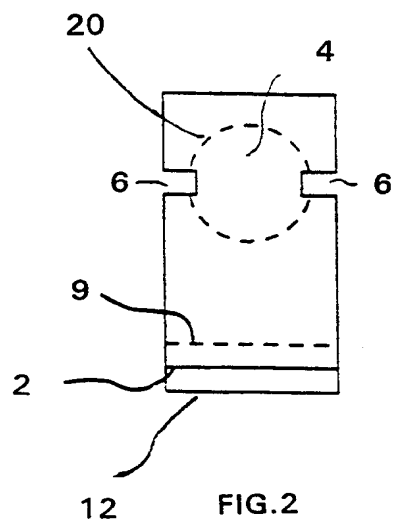
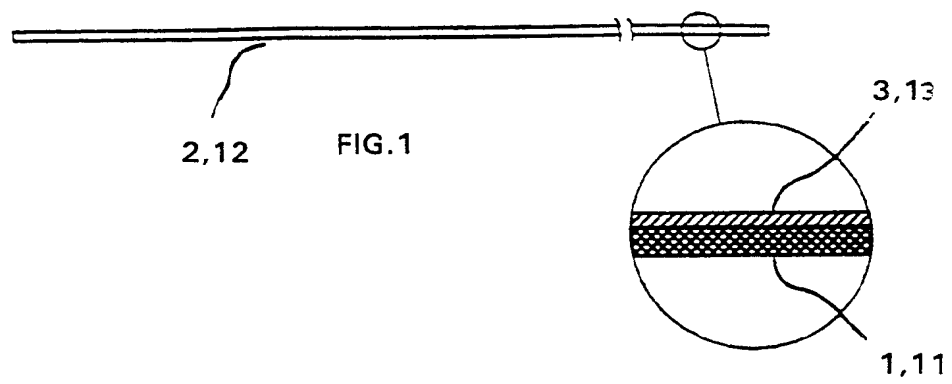
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a monitoring means adapted to monitor a property of the electromagnetic radiation passing and/or reflected through said transmissive portion, and

a means for determining whether said monitored property has reached a predetermined value indicative of the cell being filled.

- 5 27. An apparatus according to claim 26 further including means to apply a potential across the amperometric cell and detect the resultant current.
28. An apparatus according to claims 26 or 27 further including a validation means to confirm that the cell is filled with liquid sample.

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00200

A. CLASSIFICATION OF SUBJECT MATTER																						
Int Cl ⁶ : G01N 27/30																						
According to International Patent Classification (IPC) or to both national classification and IPC																						
B. FIELDS SEARCHED																						
Minimum documentation searched (classification system followed by classification symbols) IPC G01N 27/26, 27/28, 27/30, 27/403, 27/404																						
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU : IPC as above																						
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT : (TRANSPAREN: OR TRANSLUC: OR GLASS# OR PLASTIC OR CLEAR) AND (SUBSTRATE# OR ELECTRODE#) JAPIO : as per DERWENT																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
X	GB 2194112 A (MALVERN INSTRUMENTS LIMITED) 24 February 1988 abstract, page 1 lines 76-82, page 2 lines 6-14, Fig 1	1-28																				
X	Derwent Abstract Accession No. 93-140898/17, class S03, JP,A, 05080018 (RIKAGAKU KENKYUSHO) 30 March 1993 abstract	1-28																				
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"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art																			
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Date of the actual completion of the international search 26 May 1998		Date of mailing of the international search report -2 JUN 1998																				
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929		Authorized officer SOOSA GNANASINGHAM Telephone No.: (02) 6283 2172																				

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 98/00200

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Derwent Abstract Accession No. 95-026336/04, class S03, JP,A, 06310746 (HITACHI LTD) 4 November 1944 abstract	1-28
X	US 4782265 A (SCHAPER et al) 1 november 1988 column 1 lines 6-13, column 2 lines 14-34, claim 1	1-28
X	US 4254546 A (ULLERY, Jr) 10 March 1981 column 3 lines 11-15, column 9 lines 49-52 (claim 1)	1-28
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Y	EP 585933 A2 (MATSUSHITA ELECTRIC INDUSTRIAL CO LTD) 9 March 1994 column 6 lines 28-40, claim 4	1-28

Information on patent family members

PCT/AU 98/00200

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
GB	2194112	DE	3723388	JP	63045553		
US	4254546	BE	861439	BR	7707957	CA	1089946
		DE	2751393	ES	464679	FR	2373165
		GB	1559247	IL	53276	IN	148687
		IT	1091265	JP	53070781	MX	144753
		NL	7712838	ZA	7706512	US	4127424
<div>END OF ANNEX</div>							